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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,790	06/06/2001	John E. Sims	2008-US	9011

22932 7590 05/16/2003

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/876,790	SIMS ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *3-5,8,11 and 14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-2, 6-7, 9-10, 12-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I in Paper No.10, filed on 19 March 2003 is acknowledged. Applicants did not elect a single nucleotide sequence, as was required in the restriction requirement mailed on 20 February 2003 in Paper No9. However, During a telephone conversation with Patricia Anne Perkins on April 24, 2003, a provisional election was made with traverse to prosecute the nucleotide sequence of SEQ ID NO:1. Affirmation of this election must be made by applicant in responding to this Office action.

Applicants' first ground of traversal is that a protein and a DNA sequence encoding it exhibit corresponding technical features and that unity between claims to such proteins and DNAs is accepted according to administrative instructions under the PCT rules.

This ground of traversal is not found persuasive, because instant application is not a national stage applications filed under 35 U.S.C. 371, but is a continuation in part of application PCT/US99/29546. Therefore, restriction rules under 35 U.S.C. 121 apply, rather than PCT rules for lack of unity.

Applicants' second ground of traversal is that the polypeptides of SEQ ID Nos: 3, 8, 9, and 10 are identical in the region from amino acid 89 to amino acid 218, and the nucleotide sequences encoding them are also related, therefore, the claimed nucleic acids and polypeptides share a common structural property.

Firstly, the only polypeptide that comprises 218 amino acid residues is the polypeptide of SEQ ID NO:8, the polypeptide of SEQ ID Nos: 3, 9 and 10 comprise of 192, 197 and 157 amino acid residues, respectively. Secondly, Pursuant to 35 U.S.C. 121, nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, (see MPEP 2434). Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 6, 7, 9-10, 12 and 13 are drawn to the elected polynucleotide of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:3. Therefore, claims 1, 2, 6, 7, 9-10, 12 and 13 are under consideration.

Claims 3-5, 8, 11, 14-23 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested "Polynucleotide encoding IL-1 Zeta polypeptide."

2b. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, on page 4, lines 7 and 8. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code.

Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP § 608.01.

Claim objections:

3. Claims 1-2 are objected to because of the following informalities:

Claims 1, 2 recite non-elected SEQ ID Nos. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 9 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 9-10 recite "a host cell .....", which encompasses the host cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claims 9-10 be amended to recite " an isolated host cell..... .....". Appropriate correction is required.

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1, 2, 6, 7, 9-10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1, said polynuceltode encoding the polypeptide of SEQ ID NO:3, a vector comprising said polynucleotide, a host cell comprising said vector and a method of producing the encoded polypeptide by culturing said host cell, does not reasonably provide enablement for an isolated polynucleotide which hybridizes to the polynucleotide of SEQ ID NO:1 encoding a polypeptide that binds to an IL-1 R family member, or an isolated polynucleotide that encodes a polypeptide that is 80% identical to the polypeptide of SEQ ID NO:3, which binds to an IL-1 R family member, or isolated polynucleotide that encodes a fragment of the polypeptide of SEQ ID NO:3 which binds to an IL-1 R family member . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

With respect to claim 1, which recites an isolated polynucleotide that is capable of hybridizing at specific hybridization conditions, to the polynucleotide of SEQ ID NO:1, encoding a polypeptide that binds to an IL-1 R family member, the specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce polynucleotides that hybridize to the polynucleotide of SEQ ID NO:1, which encode polypeptides that bind to an IL-1 receptor family member nor does the disclosure provide criteria that explicitly enable such critical features. Furthermore, in the absence of a sufficient number of examples to

enable the scope of the claims, the specification fails to provide the necessary guidance with assurance that one of ordinary skill in the art would obtain the products that possess the desired properties. Claim 2 is overly broad in the recitation of "a polynucleotide which encodes a polypeptide that is at least 80% identical or a fragment of SEQ ID NO:3" and for reciting "....wherein said polypeptide or fragment binds to an IL-1R family member..", since no guidance is provided as to which of the myriad of polypeptide species encoded by the polynucleotide encompassed by the claim will retain the characteristics of the polypeptide of SEQ ID NO:3. The instant specification does not outline residues of SEQ ID NO:3 which are considered conservative. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The instant specification does not provide a description of a repeatable process of producing a polynucleotide encoding a polypeptide whose amino acid sequence deviates from the disclosed sequence SEQ ID NO:3 by as much as 20% or a fragment of the polypeptide of SEQ ID NO:3, that binds to an IL-1 receptor family member. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed the polypeptide of SEQ ID NO:3, which are required for functional and structural integrity of the protein. It is this additional characterization of the disclosed protein that is required in order to obtain the functional

and structural data needed to permit one to produce a polypeptide which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the quantity of experimentation to determine which of the enormous number of polynucleotides that are capable of hybridizing to the polynucleotide of SEQ ID NO:1, would encode a polypeptide that binds to an IL-1 R family member or would encode a fragment that binds to an IL-1R family member as encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little. Furthermore, the amount of embodiments corresponding to the desirable polynucleotides, may be innumerable, and the enabled embodiments amount to only the polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe any other polynucleotides encoding other than those whose amino acid sequences are shown in, SEQ ID NO:3, and since it is deemed to constitute undue experimentation to determine

all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for a polynucleotide which hybridizes to that of SEQ ID NO:1, or a polynucleotide encoding a polypeptide that is 80% to the polypeptide of SEQ ID NO:3, or a polynucleotide encoding a fragment of the polypeptide of SEQ ID NO:3, said polypeptides being able to bind to an IL-1R family member.

4b. Claims 1, 2, 6, 7, 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only discloses the polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1, and therefore the written description is not commensurate in scope with the claims drawn an isolated polynucleotide which hybridizes to the polynucleotide of SEQ ID NO:1 that encodes a polypeptide that binds to an IL-1 R family member, or an isolated polynucleotide that encodes a polypeptide that is 80% identical to the polypeptide of SEQ ID NO:3, which binds to an IL-1 R family member, or isolated polynucleotide that encodes a fragment of the polypeptide of SEQ ID NO:3 which binds to an IL-1 R family member.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Instant specification does not define the structure of polynucleotide sequences which are capable of hybridizing to the polynuceltode of SEQ ID NO:1, or those that would encode a polypeptide that is 80% identical to the polypeptide of SEQ ID NO:1. With respect to claim 2, Applicants have not delineated which residues of the polypeptide of SEQ ID NO:3 are considered to be required for the functional and structural integrity of the polypeptide of SEQ ID NO:3. Furthermore, the claims do not indicate those amino acid residues which are considered conservative which if altered would not affect the function of the protein of SEQ ID NO:3. With the exception of the polynucleotide of SEQ ID NO: NO:1, the skilled artisan cannot envision the detailed structure of the encompassed the polynucleotides or the encoded polypeptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of

nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Therefore only isolated polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1, encoding the polypeptide comprising the amino acid sequence of SEQ ID NO:3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. As a result, it does not appear that the inventors were in possession of an isolated polynucleotide which hybridizes to the polynucleotide of SEQ ID NO:1 encoding a polypeptide that binds to an IL-1 R family member, or an isolated polynucleotide that encodes a polypeptide that is 80% identical to the polypeptide of SEQ ID NO:3, which binds to an IL-1 R family member, or isolated polynucleotide that encodes a fragment of the polypeptide of SEQ ID NO:3 which binds to an IL-1 R family member

Claims 6, 7, 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 1 and 2 for the limitation set forth directly above.

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6a. Claims 1, 2, 6, 7, 9, 10, 12 and 13 are rejected under 35 U.S.C § 102(e) as being anticipated by Yang Pan (U.S. Patent 6,117,654).

Pan teaches an isolated nucleic acid that shares 68.3% identity to instant polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO: 1, a vector comprising said nucleic acid, a host cell comprising said vector and a method of producing the encoded polypeptide, (see column 22 line 37, through column 25, line 48 and claims). The nucleic acid disclosed by Pan encodes a polypeptide that shares 69% to the polypeptide of SEQ ID NO:3 of the instant application, and binds to an IL-1R family, (see column 2, lines 10-20). See attached copies of the comparison of SEQ ID NOs:1 and 3 claimed in the instant invention and the sequences of the reference (SEQUENCE COMPARISON 'A' and "B", respectively).

The polynucleotide disclosed in the Pan reference would be expected to hybridize to the polynucleotide of SEQ ID NO:1, under the hybridization conditions recited in claim 1, and it encodes a polypeptide that binds to an IL-1R family member (see column 2, lines 10-20). With respect to claim 2, Pan reference meets the fragment limitation recited in the claim. Therefore, the Pan reference clearly anticipates instant claims 1, 2, 6, 7, 9, 10, 12 and 13 in the absence of any evidence to the contrary.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
May 13, 2003

Yvonne Eyler
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